DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 10, 2014

Distal Access, LLC
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141054
Trade/Device Name: Distal Access Torque Device or Controller (Predict or Spinr)
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 24, 2014
Received: November 25, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141054

Device Name

Distal Access Torque Device or Controller (Predict or Spinr)

Indications for Use *(Describe)*

Distal Access torque devices are used to maneuver guide wires in the coronary and peripheral vasculature during interventional or diagnostic procedures. Distal Access torque devices are not intended for use in the neurovasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

510(k) Number K141054

General Provisions	**Date of Preparation:**	December 8, 2014
	Submitter Name:	Shawn P. Fojtik
	Sponsor:	Distal Access, LLC
	Address:	5010 Heuga Court, Park City, UT 84098-8514
	Telephone/	Phone (435) 602-9640
	Fax No.:	(954) 457-8038
	Email	fojtik@post.harvard.edu
	Contact Name:	Shawn P. Fojtik
	Contact Company:	Distal Access, LLC
	Address:	5010 Heuga Court, Park City, UT 84098-8514 USA
	Telephone/	(435) 602-9640
	Fax No.:	(954) 457-8038
	Email:	fojtik@post.harvard.edu
Subject Device	**Trade Name:**	Distal Access Torque Device or Controller (Predict or Spinr)
	Common Name:	Torque device / controller
	Classification Name:	Catheter Guide Wire (accessory) (74DQX; 21 CFR § 870.1330)
Predicate Devices	**Trade Name:**	Pin Vise torque device
	Common Name:	Torque device / controller
	Classification Name:	Catheter, Percutaneous (accessory) (74DQY; 21 CFR § 870.1250)
	Manufacturer:	Merit Medical Systems, Inc.
	Premarket Notification:	K936032 December 17, 1993
	Trade Name:	VSI torque device
	Common Name:	Torque device / controller
	Classification Name:	Catheter Guide Wire (accessory) (74DQX; 21 CFR § 870.1330)
	Manufacturer:	Vascular Solutions, Inc.
	Premarket Notification:	K100093 April 30,2010

Device Description
Manually rotating, spinning, and torqueing wires, guidewires, catheters, and other devices are common during interventional and diagnostic procedures. The Distal Access Torque Device (Predict / Spinr Controller) is a single-use hand-held manually operated high-performance torque device / controller used to maneuver difficult-to-grasp devices including guidewires during interventional or diagnostic procedures.

The Predict's design allows for predictable and controllable rotation of a device clockwise with counterclockwise return to its original orientation. Clockwise and counterclockwise rotations are manually controlled so the Predict rotates the same number of rotations in one direction as the other. Similar to the predicates, the user manually advances and retracts the Predict torque device forward and backward to introduce or remove the connected device from the body. Also, identical to the predicates, the Predict may be connected to a device already in the body.

Same as the predicates, a device, including a guidewire, is loaded into the Predict 0.014 – 0.039" by inserting the proximal end of the device into the distal end of the Predict's cap. The Predict locks down on the device when the user rotates the collet cap clockwise, forcing the industry standard designed collet to grip onto the device. The device is released when the user rotates the cap counterclockwise to loosen the collet's grip on the device.

Once a device is connected, the Predict manually and predictably rotates devices between 3 and 5 times clockwise and counterclockwise as per the labeled number of rotations. Rotation is manually controlled by the user's finger, thumb and hand. Also, identical to predicates, the Predict does not use electrical power or software.

Similar to predicate devices, industry standard components and materials are used:
- Medical grade polycarbonate (Makrolon) sleeve, grip, body, screw, slider, and cap components.
- Stainless steel spring.
- Industry standard collet design.
- ISO 10993 compliant medical grade Loctite adhesive and NuSil Lubricant.

Predicts do not add any new materials or manufacturing processes to molding or assembly.

Indication for Use
Distal Access torque devices are used to maneuver guide wires in the coronary and peripheral vasculature during interventional or diagnostic procedures. Distal Access torque devices are not intended for use in the neurovasculature.

Guidance Documents
Verification and validation tests have been performed in accordance with the FDA's Design Control requirements identified in 21 CFR §820.30. The following guidance documents and standards were used in conjunction with in-house protocols to determine that the new Predict device is substantially equivalent to the predicated device(s):

ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing*

ANSI/AAMI/ISO 11135-1:2007*, Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*

AAMI ISO TIR 11135-2:2008, *Sterilization of health care products- Ethylene oxide - Part 2:*

Guidance on the application of ANSI/AAMI/ISO 11135-1

ANSI/AAMI/ ISO 11607-1: (2006)/(R)2010, *Packaging for terminally sterilized medical devices- Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ANSI/AAMI/ ISO 11607-2: (2006)/(R)2010, *Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing, and assembly processes*

ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F 1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Sterility)

Testing

In addition, the following attributes were evaluated in accordance with test protocols to determine the relative performance of the new Predict device with the predicate torque devices:

- Axial wire retention force;
- Collet release testing;
- Collet slip torque;
- Cap dimensions;
- Collet insertion force;
- Rotational speed;
- Comparative torque testing;
- Screw rotations;
- Wire pull tests;
- Spring force and dimensions;
- Slider length and sleeve view port test;
- Rotational speed test;
- Comparative torque tests;
- Axial force and wire movement versus predicate;
- Collet slip torque comparison to predicate;
- Evaluation of collet grip strength under simulated use;
- Package seal strength and integrity.
- Biocompatibility: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Pyrogenicity, and Hemocompatibility.

The Predict subject device met all predetermined acceptance criteria identified in test protocols created to evaluate conformance with the relevant requirements of the above listed standards, guidance documents, and in-house protocols demonstrating that identified potential risks and hazards have been acceptably controlled and that the safety and/ or performance of the new device are equivalent to those of the cited predicate device(s).

Clinical testing.

Not required for this device.

Summary of Substantial Equivalence

Based on a comparison of labeling, including intended and indicated uses, of the new and predicate devices; results of performance and safety tests; and an acceptable biological and toxicological risk associated with the use of the Predict torque device; Distal Access concludes that its new torque devices perform as well as or better than, the identified predicate devices, and can therefore be considered substantially equivalent.

The conclusions drawn from the nonclinical tests demonstrate that the Predict device is substantial equivalent to the legally marketed Merit Pin Vice and VSI torque devices.